

Notice of Allowability

Application No.

10/615,329

Examiner

Zachary C. Tucker

Applicant(s)

HASHIMOTO ET AL.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 13 April 2007.
2. ☒ The allowed claim(s) is/are 111-134.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/939,374.
 - ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>30Mar07</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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Response to Amendment

As requested in the correspondence filed 13 April 2007 (hereinafter "present amendment"), which is in reply to the Office action mailed on 2nd October 2006 (hereinafter "previous Office action"), claims 1-110 have been cancelled and new claims 111-134 have been added.

Requirement for Restriction

Because the claims corresponding to the elected invention, designated Group I (original claims 42-93, now claims 111-113) in the Requirement for Restriction mailed 16 August 2006, are in allowable form pursuant to the present amendment, withdrawn claims from Group II as set forth in the Requirement are eligible for rejoinder.

Present claims 114-134 correspond to the subject matter identified in Group II of the Requirement for Restriction. Claims 114-134 are hereby rejoined and the Requirement for Restriction as set forth in the Office action mailed in this application 16 August 2006 is hereby WITHDRAWN.

Status of Obviousness-Type Double Patenting

In the previous Office action, claims 42, 44, 47, 48-51, 53, 54, 56-58, 60, 61, 64, 68-73, 74, 76, 79-88 and 90 were rejected under the judicially-created doctrine of obviousness-type double patenting (ODP), as being unpatentable over claim 1 of U.S. Patent No. 7,112,600.

The ODP rejection is moot in principle due to the rejected claims' being cancelled in the present amendment. New claims drawn to the fused ring compounds according to instant claims 111, 112 and 113, however, would be embraced by claim 1 of the patent, but applicants' filing of a disclaimer over the terminal portion of the term of any patent

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granted on the instant application which would extend beyond the full statutory term of the identified patent, with the added stipulation that neither patent shall be enforceable if both are not commonly owned has obviated the ODP rejection. The ODP rejection over US 7,112,600 is hereby withdrawn.

Status of Claim Rejections - 35 USC § 112

In the previous Office action, claims 42-93 were rejected under the second paragraph of this statute because the metes and bounds of the subject matter sought to be patented was deemed not to be clear and well-defined.

Since claims 42-93 have been cancelled, the rejection is moot.

New claims added by the present amendment do not include the deficiencies noted in the finding of indefiniteness. Applicants' argument pertaining to the definitions of n', ring B', Z' and w' is persuasive. New claims 111, 112 and 113 include a more concrete description of what is intended by the terms "heterocycle" and "heterocyclic group."

Erratum: The last sentence on page 6 of the previous Office action, in the section headed "Claim Rejections - 35 USC § 112" was unintentionally printed.

Claim Objections

In the previous Office action claim 59 was objected to (in addition to the rejection of that claim) for a spelling error. The matter is moot in view of the cancellation of claim 59.

Information Disclosure Statement

Applicants' provision of the references cited by applicants in the Information Disclosure Statement but not found in the application file wrapper is noted with appreciation. A newly signed, initialed and dated PTO-1449 form corresponding to the Information Disclosure Statement is supplied with this Notice of Allowability.

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Allowable Subject Matter

Claims 111-134 are allowed.

Compounds according to allowed claims 111, 112 and 113 are novel and unobvious over the prior art. A summary of the closest prior art was provided in pages 10-12 of the previous Office action. Methods according to claims 117-134 are therefore also similarly novel and unobvious. A full English translation of the Russian article authored by Khaliullin et al, from Bashkirskii Khimicheskii Zhurnal, vol. 4(4), pages 59-62 (1997), is included with this Notice of Allowability. This reference is the single closest prior art disclosure. If the piperazine ring moiety in the structure diagram shown in the abstract for the Khaliullin et al article were the aromatic form of that heterocycle, a pyrazine ring in other words, the claims would not be patentable. Khaliullin et al is cited in the Information Disclosure Statement filed by applicants, but no translation was provided. A review of the translation of this important reference revealed that it offers no suggestion to replace the piperazine ring with any aromatic substituent, heterocyclic or otherwise. Thus, the compounds of the present invention are indeed patentable over the closest prior art.

Compounds of the invention are inhibitors of the RNA-dependent RNA polymerase of the hepatitis C virus. Treatment of hepatitis C with drugs having such activity had been already established and understood in the medical arts at the time the invention was made, so the claimed methods of treating hepatitis C comprising administering compounds of the present invention are deemed enabled and compliant with 35 U.S.C. 112, first paragraph.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany

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the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

All Post-Allowance Correspondence concerning this application must be mailed to:

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Or you can fax them to the Office of Patent Publications at 703-872-9306, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312; information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at (703) 305-8027. The Notice of Allowance also has an insert containing contact information on other items, including Issue Fees, receipt of formal drawings and the status of the application.



ZACHARY C. TUCKER
PRIMARY EXAMINER